

Remarks

In the current Office Action, the Examiner has rejected Claims 1-10 under 35 U.S.C. § 112, as being indefinite. The Examiner further rejected Claims 1-10 under 35 U.S.C. § 103(a), as being allegedly obvious in view of several prior art references discussed therein.

Applicant asserts that, in view of the foregoing amendments to the claims and the following remarks, the rejections under §§ 112 and 103(a) should be withdrawn.

I. The requested amendments to the claims render the rejections under 35 U.S.C. § 112 moot.

The Examiner rejected Claims 1-10 under 35 U.S.C. § 112 because the term “predominant amount,” used in both independent Claims 1 and 5, is a relative term which renders the claims indefinite. Applicant has amended Claims 1 and 5 and deleted this phrase therefrom, which was an unnecessary and superfluous limitation.

The Examiner further rejected Claims 2, 4, 6, and 7 because these claims recited “octoxynol-9,” which the Examiner contends is a trademark or tradename. Upon information and belief, Applicant respectfully disagrees with the Examiner’s assertion that “octoxynol-9” is a trademark of a third party. Rather, “octoxynol-9” is a common chemical name (not a trademark) for poly(oxy-1,2-ethanediyl), alpha-(4-(1,1,3,3-tetramethylbutyl)phenyl)-omega-hydroxy-. See, e.g., **Exhibit A**. This notwithstanding, for the purpose of facilitating prosecution and placing the present application in a condition for allowance, Applicant has amended Claims 2, 4, 6, and 7 to replace “octoxynol-9” with “poly(oxy-1,2-ethanediyl), alpha-(4-(1,1,3,3-tetramethylbutyl)phenyl)-omega-hydroxy-.”

In view of the foregoing, Applicant respectfully requests that the rejections under § 112 be withdrawn.

II. The rejections under 35 U.S.C. § 103(a) should also be withdrawn.

A. Garg et al. does not disclose treating vaginitis using the claimed methods -- it *teaches away* from Claims 5-10.

The primary reference the Examiner relies upon in rejecting the originally-filed claims is the article “Compendium of Pharmaceutical Excipients for Vaginal Formulations” by Garg et al. (referred to herein as “Garg et al.”). Applicant respectfully draws the Examiner’s attention to the fact that Claims 5-10 are directed to methods for the treatment of vaginitis.

The specific portions of Garg et al. that the Examiner cites not only fail to disclose treating vaginitis with such compositions, Garg et al. actually *teaches away* from the claimed methods. Vaginitis is “an inflammation of the vaginal mucosa and often associated with an irritation or infection of the vulva leading to vulvovaginitis.” *See, e.g., Exhibit B*.

Garg et al. disclose a host of different vaginal formulations, which are described to be useful for a wide range of different applications, namely, spermicidal contraceptives, cervicitis, vulvovaginitis, vaginal irritation, vaginal acidity maintenance, microbicides, anti-trichomoniasis, cervical ripening, bacterial vaginosis, yeast infection treatments, anti-viral treatments, progesterone supplements, and the list goes on. (Garg et al., p.16-17). Each different formulation disclosed in Garg et al. is correlated with its own indication or therapeutic use. (*Id.*).

The Examiner cites the following composition from Garg et al. on page 3 of the Office Action:

Filed - March 26, 2008

Massengill Towel	SmithKline Beecham	Lactic acid, water, sodium lactate, potassium sorbate, O-9, EDTA, cetylpyridinium chloride, fragrance	Cleanse external vaginal area
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(Garg et al. p.17). Garg et al. teach that the above formulation is designed to “cleanse [the] external vaginal area” -- not to treat vaginitis or vulvovaginitis. This is a significant and critical distinction between Garg et al. and Claims 5-10 (claiming methods for the treatment of vaginitis).

Importantly, other dissimilar formulations in Garg et al. are described to be useful for treating vaginitis (vulvovaginitis), but not the formulation that the Examiner relies upon. Hence, Garg et al. recognizes that certain vaginal-related formulations will be useful for treating vaginitis (vulvovaginitis), but not the formulation that the Examiner cites. For example, Garg et al. teaches that the following two formulations may be used to treat vaginitis:

AVC	Cream, suppository	Monarch	Cream: lactose, propylene glycol, stearic acid, diglycol stearate, methyl paraben, propyl paraben, triamine, lactic acid Suppository: polyethylene glycol 400 and 3350, Polysorbate 80, glycerin, lactic acid, cover made up of gelatin, glycerin, water, methyl paraben, propyl paraben, color	Vulvovaginitis caused by C. albicans
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Sultrin	Cream	Ortho-McNeil Pharmaceutical	Cetyl alcohol, cholesterol, diethylaminoethyl stearamide, glyceryl monostearate, lanolin, lecithin, methyl paraben, peanut oil, phosphoric acid, propylene glycol, propyl paraben, water, urea, stearic acid	Vaginitis caused by Gardnerella
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(Garg et al., p.16, 17).

Since Garg et al. does teach some formulations that may be used to treat vaginitis, the absence of such indication from the description of the formulation that the Examiner cites and relies upon in the current Office Action suggests that it may not be used to effectively treat vaginitis. In other words, the portion of Garg et al. cited by the Examiner actually *teaches away* from Claims 5-10. The significance of a prior art reference *teaching away* from a claimed invention was reinforced in the fairly recent and well-known *KSR* decision. *KSR v. Teleflex*, 127 S.Ct. 1727 (2007) (“when the prior art teaches away from combining certain known elements, discovery of a successful means

of combining them is more likely to be non-obvious.”). For this reason alone, Claims 5-10 should be allowed to issue.

B. The invention of Claims 1-10 exhibits unexpected results -- it has been shown to effectively control odor *without* the use of a fragrance.

The number of claim limitations that are not satisfied by the prior art cited in the pending Office Action is telling. The Office Action correctly states that the prior art relied upon “[d]oes not explicitly teach the amount of the odor absorbing agent, or amount of antiseptic cetylpyridinium” (an antiseptic), yet the Office Action summarily concludes that Claims 1-10 are obvious. (Office Action, p.4). The type and quantity of odor absorbing and antiseptic agents are important features of the claimed invention, which the Examiner candidly admits is not taught by the prior art.

For example, in addition to the ability of the claimed invention to be capable of treating vaginitis (which clearly is not taught by the prior art), the invention is also very effective in combating undesirable odor - even *without* the use of fragrance. More particularly, a device of the present invention which comprises an absorbent fabric impregnated with a liquid consisting essentially of 5% saccharomyces ferment, 0.50% oxytoxynol-9, 0.2% potassium sorbate, 0.2% cetylpyridinium chloride, 0.10% disodium EDTA, and 0.05% lactic acid was tested for its ability to control odor in accordance with an E-544-99 standardized protocol.

The test results demonstrated that the present invention is capable of reducing “headspace feminine odor” by 74% -- a truly significant reduction in “headspace feminine odor.” Importantly, it should be appreciated that the device / liquid combination was shown to impart these odor-control properties *without* the use of a fragrance. The discrete portion of Garg et al. that is cited in the current Office Action

requires the presence of, *inter alia*, a “fragrance.” Thus, in response to the Examiner’s statement that “absent some demonstration of unexpected results” the claimed invention is obvious, Applicant respectfully submits that the ability of the claimed invention to reduce feminine odor to such a significant degree (without the use of a fragrance) is indeed an unexpected and surprising result. (Office Action, p.4).

The methodology employed during, and results achieved from, the testing of certain embodiments of the present invention are described in further detail in **Exhibit C** hereto, which is submitted under 37 C.F.R. § 132.

C. At the very minimum, Claims 4 and 7 are allowable.

The Examiner asserts that the “picture claims” of Claims 4 and 7 are also obvious. Such a conclusion runs afoul of well-established law. The Examiner contends that Claims 4 and 7 are obvious in view of Garg et al., U.S. Patent Application Publication 2002/0142690 (“US ‘690”), and the article “Natural Deodorant” by Carrubba, Inc. (“Carrubba Inc.”). The Office Action correctly notes that neither Garg et al., nor US ‘690, disclose using *saccharomyces* ferment to control odor. The Examiner suggests that such component is taught by Carrubba Inc.

Claims 4 and 7 are patentable over these three references for at least two reasons, namely, (1) these references still do not disclose all of the limitations recited in Claims 4 and 7 and (2) the Examiner fails to take into account that Claims 4 and 7 employ a “*consisting essentially of*” transitional phrase (thereby excluding significant amounts of other agents), which none of the prior art references even contemplate. Moreover, Claim 7, which is drawn to a method for treating vaginitis, is further patentable over these three references in view of the remarks in Section IIA above.

(1) The prior art does not disclose, or suggest, all of the elements of Claims 4 and 7.

The Office Action correctly states that the prior art “[d]oes not explicitly teach the amount of the odor absorbing agent, or amount of antiseptic cetylpyridinium” (an antiseptic). (Office Action, p.4). The Office Action then concludes that, despite such gaps in the prior art, the amounts of these specific ingredients in a composition is a result effective parameter and, therefore, the pending claims are obvious.

Such reasoning does not contain the necessary legal basis to support the conclusion that Claims 1-10 are obvious, much less Claims 4 and 7 in particular. The conclusion that an invention is obvious must be based on facts. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). When a conclusion of obviousness is not based on facts, it cannot stand. *Ex parte Porter*, 25 USPQ2d 1144, 1147 (BPAI 1992). As described above, not only does the prior art fail to disclose all of the limitations of Claims 4 and 7 (*i.e.*, the specific quantities of the odor controlling and antiseptic agents), the prior art actually requires the presence of multiple agents which are excluded under Claims 4 and 7 (as described below).

(2) Claims 4 and 7 are “consisting essentially of” claims.

Perhaps most importantly, the current Office Action fails to recognize that Claims 4 and 7 employ the transitional phrase “consisting essentially of.” It is well-established law that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. See MPEP § 2111.03 (citing *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)).

In rejecting Claims 4 and 7, the Examiner cites the combination of Garg et al., presumably the formulation reproduced below from page 17 of Garg et al., the Carrubba, Inc. article for the use of saccharomyces ferment, and US '690 for, essentially, impregnating a substrate with a liquid containing octoxynol-9. However, the Garg et al. formulation cited by the Office Action further includes sodium lactate and fragrance - neither of which are recited in Claims 4 and 7. (See the excerpt of Garg et al., p.17, reproduced below).

Massengill	Towel	SmithKline Beecham	Lactic acid, water, sodium lactate, potassium sorbate, O-9, EDTA, cetylpyridinium chloride, fragrance	Cleanse external vaginal area
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Again, Claims 4 and 7 employ the transitional phrase “consisting essentially of” and, therefore, exclude the material additions of sodium lactate and fragrance, as disclosed in the cited prior art. As described above, this is an important limitation of Claims 4 and 7, insofar as the present invention has been shown to control odor *without* the use of a fragrance (which merely disguises or “covers up” an undesirable odor).

Exhibit C.

As the Examiner should appreciate, it is well-settled law that when a claim excludes an element (*e.g.*, a fragrance) that a reference (*e.g.*, Garg et al.) requires, that is the epitome of unobviousness. *See, e.g., In re Freed*, 165 USPQ 570, 572 (CCPA 1970); *In re Duva*, 156 USPQ 90, 94 (CCPA 1967); *In re Fischer*, 179 USPQ 304, 305 (CCPA 1973); *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983); *Ex parte Cordova*, 10 USPQ2d 1949, 1951 (BPAI 1988); *Ex parte Grasselli*, 231 USPQ 393, 394 (Bd. App. 1983); and *Ex parte Kaiser*, 189 USPQ 816 (Bd. App. 1975).

Moreover, since the formulation relied upon in Garg et al. discloses the use of a “fragrance,” it can be said that such reference also “teaches away” from Claims 4 and 7,

insofar as these claims (1) exclude the use of fragrances and (2) such devices and methods of the present invention have been shown to be effective in controlling odor without the use of a fragrance. MPEP § 2145 (“Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the invention.”)(citing *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992)); *see also* , **Exhibit C**, Declaration submitted under 37 C.F.R. § 132.

The “fragrance” component of the cited Garg et al. formulation is not a ubiquitous component that one would expect these types of vaginal-formulations to necessarily include. For example, among the more than 50 different formulations listed on pages 16-17 of Garg et al., only three (3) formulations recite the use of a fragrance (one of these three formulations being the formulation that the Examiner cites).


The key reference that the Examiner relies upon expressly includes a fragrance (and sodium lactate) - both are agents that would materially affect the subject composition and both of which are expressly excluded from Claims 4 and 7 (vis-à-vis the use of the “consisting essentially of” transitional phrase). For this additional reason, the rejection of Claims 4 and 7 should be withdrawn.

III. Conclusion

In view of the Amendments to the Claims, Applicant respectfully requests that the current rejection under § 112 be withdrawn. In addition, Applicant respectfully requests that the rejections under § 103(a) be withdrawn, because (1) Garg et al. actually *teaches away* from Claims 5-10, insofar as these claims are directed to methods for treating vaginitis (and Garg et al. suggest that the cited formulations would not be useful for such

indications); (2) Claims 1-10 do exhibit unexpected properties not disclosed in the prior art, namely, the ability to control feminine odor without the use of a fragrance, and (3) Claims 4 and 7 employ the well-known "consisting essentially of" transitional phrase, which excludes the presence of fragrances, sodium lactate, and the other agents which are disclosed in the prior art (but not in Claims 4 and 7).


Respectfully submitted,


James Surber

Extension of Time Under 37 C.F.R. § 1.136(a)

Please grant a three-month extension of time for responding to the Office Action mailed September 27, 2007. With the requested extension, the deadline for a response will be March 27, 2008. A check is enclosed herewith for the Extension of Time fee under 37 C.F.R. § 1.136(a).

Respectfully submitted,



James Surber